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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,902	09/27/2001	Mark S. Roby	2791	3232

7590 05/21/2003

Chief Patent Counsel
United States Surgical
Division of Tyco Healthcare Group LP
150 Glover Avenue
Norwalk, CT 06856

EXAMINER

PHANIJPHAND, GWEN G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/21/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,902

Applicant(s)

ROBY ET AL.

Examiner

Gwen Phanijphand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections – 35 U.S.C. 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 22, claim 22 states, “the silicone-containing coating comprises an interpenetrating network.” This phrase is indefinite, and examiner could not find support in the specification.

Regarding claim 24, claim 24 states, “whereby the surgical needle has a penetration force on a fifth pass through tissue.” This phrase is indefinite because it is unclear the type of tissue that is being used to measure the needle’s penetration force.

Claim Rejection – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,959,068 to Bendel et al.

Regarding claim 24, Bendel et al. disclose a surgical needle having reduced penetration force comprising a surgical needle having an acid-treated surface (col. 1, ll. 67-68) and a

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silicone-containing coating on at least a portion of the acid treated surface (col. 2, ll. 7-8). The surgical needle is capable of having a penetration force on a fifth pass through a tissue that is at least 10% less than the penetration force on a fifth pass through a tissue of a needle having the same silicone-containing coating but that is not acid treated. The needle's surface is activated by an acid, which helps the silicone coating bind to the surface (see U.S. Patent No. 6,025,025: col. 2, ll. 66-67; col. 3, ll. 1-11). The better the silicone coating binds to the surface, the more lubricous the needle is and the lesser the penetration force will be.

Claim Rejections – 35 U.S.C. 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,959,068 to Bendel et al. in view of U.S. Patent No. 5,928,268 to Butwell et al.

Regarding claim 20, Bendel et al. disclose an article of manufacture comprising a surgical needle (Abstract). At least a portion of a surface of the surgical needle is acid-treated (col. 1, ll. 67-68), and a silicone-containing coating is applied over the acid-treated portion of the surgical needle (col. 2, ll. 7-8). Bendel et al. do not disclose the needle having a tip portion, a body portion and suture attachment portion. It is well known for a surgical needle to have a tip portion, a body portion, and a suture attachment portion. Butwell et al. disclose in Fig 1 a needle with a tip (18), a body (20), and a suture attachment (16) portion. It would have been well known to one having ordinary skill in the art at the time of the invention that the needle of

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Bendel et al. would further comprise a tip portion and suture attachment portion for use in surgery.

4. Claims 20, 22, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,025,025 to Bartrug et al. in view of U.S. Patent No. 5,258,013 to Granger et al.

Regarding claim 20, Bartrug et al. disclose an acid treating a metal (col. 7, ll. 12-14) and then applying a silicone coating over the acid-treated portion (col. 2, ll. 16-36; col. 3, ll. 2-16; col. 7, ll. 27-49, ll. 61-67; col. 8, ll. 1-14). Bartrug, however, do not disclose a needle possessing an axial bore for receiving a suture as the metal that is treated with the acid and then silicone. Granger et al. disclose a needle possessing an axial bore that is also coated with silicone. It is well known that a needle is a metal device and that it would be advantageous to coat a needle with a coating that increases the needle's lubricity. It would have been well known to one having ordinary skill in the art at the time of the invention to include a suturing needle as a metal device that is treated with a coating to enhance lubricity.

Regarding claims 22 and 26, Bartrug et al. disclose the silicone-containing coating comprises an interpenetrating network (col. 7, ll. 61-67; col. 8, ll. 20-24).

Regarding claim 24, Bartrug et al. disclose a metal surface that is acid treated and contains a silicone coating on at least a portion of the acid-treated surface. Bartrug et al. further disclose that the silicone coating bonds to the acid activated surface better than if the surface was not activated by acid (col. 2, ll. 66-67; col. 3, ll. 1-11). Hence if the silicone coating is better bonded to the surface of the metal and silicone increases the lubricity (water resistance) of the metal, then the metal that is acid treated will have less penetration force as it passes through tissue than the metal that is not acid treated. Bartrug et al., however, do not disclose the metal

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surface being a needle. Granger et al. disclose a needle that is coated with silicone. It is well known that a needle is a metal device and that it would be advantageous to coat a needle with a coating that increases its lubricity. It would have been well known to one having ordinary skill in the art at the time of the invention to include a needle as a metal device that is treated to increase lubricity.

5. Claims 21, 23, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,025,025 as applied to claim 20 and 24 above, and further in view of U.S. Patent No. 5,258,013 to Granger et al.

Regarding claims 21 and 25, Bartrug et al. lists silicone coatings (col. 7, ll. 26-49) that are used to increase water resistance and hence increase lubricity but do not disclose the coating comprising aminoalkyl siloxane. Granger et al. disclose using aminoalkyl siloxane, a well-known silicone coating for increasing lubricity and thus decreasing penetration force of a needle. It would have been obvious to one having ordinary skill in the art at the time of the invention to include aminoalkyl siloxane in the lists of silicone coatings of Bartrug et al., since aminoalkyl siloxane is a commonly used silicone to increase lubricity.

Regarding claims 23 and 27, Bartrug et al. disclose an article of manufacture wherein the silicone-containing coating comprises a copolymer of a silicone (Bartrug et al. lists the coatings in col. 7, ll. 27-49) and a second siliconization material (col. 7, ll. 61-67; col. 8, ll. 1-14) that are used to increase lubricity, but do not disclose that the first polymer being aminoalkyl siloxane. Granger et al. disclose using aminoalkyl siloxane, a silicone coating, for increasing lubricity and thus decreasing penetration force of needle. It would have been obvious to one having ordinary skill in the art at the time of the invention to include aminoalkyl siloxane in the lists of silicone

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coatings of Bartrug et al., since aminoalkyl siloxane is a commonly used silicone coating to increase lubricity.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,536,582 to Prasad et al.

U.S. Patent No. 5,266,359 to Spielvogel

U.S. Patent No. 6,015,398 to Arimatsu et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gwen Phanijsphand whose telephone number is 703-305-4845. The examiner can normally be reached on Mon-Fri.

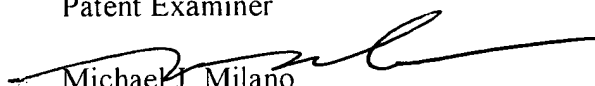
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

GP
May 11, 2003

GP

Gwen Phanijsphand
Patent Examiner


Michael J. Milano
Supervisory Patent Examiner
Technology Center 3700